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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,412	01/22/2001	Ruowen Ge	1781-0215P	7335

2292 7590 03/08/2007

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

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mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/766,412	GE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-8,10,13-16,19,20,25-27 and 29-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-8,10,13-16,19,20 and 29* is/are rejected.

7)☒ Claim(s) *25-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF THE PRE-APPEAL BRIEF REQUEST CONFERENCE, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The pre-appeal brief request conference and remarks filed 01/16/07 are acknowledged, entered and considered. Claims 1, 2, 6-8, 10, 13-16, 19, 20, 25-27 and 29-32 are now pending in the application of which claims 30-32 are withdrawn for election by original presentation for the reasons of record. Thus, the Office action is directed to the merits of claims 1, 2, 6-8, 10, 13-16, 19, 20, 25-27 and 29 as per elected invention. The rejection under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's remarks filed 01/16/07. The Finality of the previous Office action is withdrawn in view of the following new grounds of rejections:

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/25482.

The reference of WO 94/25482 ('482 patent) on page 27, lines 22-24 discloses a structure of a polypeptide having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide as claimed in independent claim 1 and dependent claim 29 or the peptide has a length of 9-20 amino acids as claimed in claim 7. Reference SEQ ID NO:45 (i.e., YPDEIEYIFKPS) of '482 patent discloses a structure of a peptide having 12 amino acid residues without any cysteine residues and therefore does not form disulfide bonds as directed to claims 1 and 6-8. On page 7, lines 1-18, the '248 patent states that the analogs (disclosed peptide) can mimic or antagonize an activity of a biologically-active polypeptide, such as anti-tumor activities, or inhibiting angiogenesis, as such meets the limitations of claims 19 and 20. The above biologically-active polypeptides (analogs) can be combined with a variety of pharmaceutically acceptable carriers to from a pharmaceutical composition as disclosed on page 12, lines 30 to page 13, lines 14, and this formulation can be administered at dosage of 60 to 120 μg as recited on page 21, line 24 which overlaps with the unit dose of 20 μg/kg/day to 2 mg/kg/day of claims 14, 16 and meet the limitations of pharmaceutical compositions of claims 13 and 15.

With respect to the functional limitation of the assay, it is inherent for peptides having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide to exhibit an IC_{50} of 20 μM or less in a bovine aorta endothelial cell proliferation assay or exhibits inhibition of angiogenesis in a chick chorioallantoic membrane assay

of at least 30% at a dose of 50 μg/coverslip or at least 50% at a dose of 10 to 25 μg/coverslip because the reference of '248 patent teaches the identical compound/composition and would therefore be expected to have the identical properties and functions(s); absent of evidence to the contrary, the claimed peptide, pharmaceutical compositions and methods of use thereof anticipates claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 as drafted.

CLAIMS REJECTION-35 U.S.C. § 102(a)

3. Claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by JP09301888A (English abstracts from JP and DERWENT are provided).

The reference of JP09301888 ('888 patent) on page 4, discloses a structure of a polypeptide having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide as claimed in independent claim 1 and dependent claim 29 or the peptide has a length of 9-20 amino acids as claimed in claim 7. Reference SEQ ID NO:26 (i.e., YPDEIEYIFKPS) of '888 patent discloses a structure of a peptide having 12 amino acid residues without any cysteine residues and therefore does not form disulfide bonds as directed to claims 1 and 6-8. In the English abstract of JP discloses an anticancer agent administered as a pharmaceutical formulation at dosage of 01-100 mg/kg body weight/day, which overlaps with the unit dose of 20 μg/kg/day to 2

mg/kg/day of claims 14, 16, and meet the limitations of pharmaceutical compositions of claims 13 and 15.

With respect to the functional limitation of the assay, it is inherent for peptides having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide to exhibit an IC_{50} of 20 μM or less in a bovine aorta endothelial cell proliferation assay or exhibits inhibition of angiogenesis in a chick chorioallantoic membrane assay of at least 30% at a dose of 50 μg/coverslip or at least 50% at a dose of 10 to 25 μg/coverslip because the reference of '888 patent teaches the identical compound/composition and would therefore be expected to have the identical properties and functions(s); absent of evidence to the contrary, the claimed peptide, pharmaceutical compositions and methods of use thereof anticipates claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 as drafted.

4. Claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by JP10087509A (English abstracts from JP and DERWENT are provided).

The reference of JP10087509 ('509 patent) on page 6, discloses a structure of a polypeptide having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide as claimed in independent claim 1 and dependent claim 29 or the peptide has a length of 9-20 amino acids as claimed in claim 7. Reference SEQ ID

NO:26 (i.e., YPDEIEYIFKPS) of '509 patent discloses a structure of a peptide having 12 amino acid residues without any cysteine residues and therefore does not form disulfide bonds as directed to claims 1 and 6-8. In the English abstract of JP discloses a tumor metastasis inhibitor administered as a pharmaceutical formulation at dosage of 01-100 mg/kg body weight/day, which overlaps with the unit dose of 20 μg/kg/day to 2 mg/kg/day of claims 14, 16, and meet the limitations of pharmaceutical compositions of claims 13 and 15.

With respect to the functional limitation of the assay, it is inherent for peptides having a length from 7-20 amino acids long and contains a pair of proline residues at least one of which is a terminal residue or a residue penultimate to a terminus of the peptide to exhibit an IC_{50} of 20 μM or less in a bovine aorta endothelial cell proliferation assay or exhibits inhibition of angiogenesis in a chick chorioallantoic membrane assay of at least 30% at a dose of 50 μg/coverslip or at least 50% at a dose of 10 to 25 μg/coverslip because the reference of '509 patent teaches the identical compound/composition and would therefore be expected to have the identical properties and functions(s); absent of evidence to the contrary, the claimed peptide, pharmaceutical compositions and methods of use thereof anticipates claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 as drafted.

OBJECTION TO CLAIMS, ALLOWABLE SUBJECT MATTER

5. Claims 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION AND FUTURE CORRESPONDANCE

6. Claims 1, 2, 6-8, 10, 13-16, 19, 20 and 29 are rejected, claims 25-27 are objected and claims 30-32 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON WEBER
SUPERVISORY PATENT EXAMINER

AAM Mohamed/AAM
February 28, 2007